Aventis Pasteur

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01N-0464
Vaccine Adverse Event Reporting System; Revised Form VAERS-2 [66 FR 58153, November 20, 2001]

21 January 2002

Dear Sir/Madam:

Aventis Pasteur Inc. would like to thank you for the opportunity to comment on the above-referenced proposed "Vaccine Adverse Event Reporting System; Revised Form VAERS-2." The form had been revised by deleting fields that FDA considers redundant or unnecessary, and by adding or revising data fields to ensure reporting clarity. We offer the following comments/suggestions for your consideration.

General Comments

Print is rather small. Moving or eliminating the margins could accommodate the additional room required by larger font sizes.

Boxes don't leave room for much information on prior history; may we suggest wording to the effect those text fields can be continued on the back of the form or on auxiliary separate pages.

Box A: Patient Information

Line 2. Parent/Guardian Name
Place line 2, Parent/Guardian Name, at bottom of Box A following Race/Ethnicity. Parent/Guardian Name field's current location suggests that Parent/Guardian Name may be submitted as the "Patient" erroneously.

Line 4. Patient's Occupation
This information is rarely received on spontaneous reports, especially those for children. It is of possible marginal value relating to the AE. As such, it is not worth the human, capital or programming resources to capture and report.

Date of Birth Box
Suggest renaming to "Date of Birth of Patient" (or Pt. Date of Birth) otherwise parent/guardians may enter their birth date in error.

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C 4

Age at vaccination Box
Suggest renaming to "Patient Age at vaccination" (Pt. age at vaccination).

Date of Birth and Age at vaccination Boxes
Shouldn't these fields be numbered like the other fields?

Line 11. Race/Ethnicity
This information is rarely received on spontaneous reports. It is of possible marginal value relating to the spontaneous AE. As such, it is not worth the human, capital or programming resources to capture and report.

Box B: Vaccine Provider Information

Line 1. County where vaccine was administered:
Suggest placing "County" in bold type or otherwise emphasizing "County." Reporters may be tempted to enter their country.

Box 7. Vaccine was administered at:
Box 8. Vaccine was purchased by provider with:
This information is inconsistently supplied in spontaneous reports to manufacturers. It is of marginal value to the AE report. As such, it is not worth the human, capital or programming resources to capture and report. Suggest removing Box 7 and Box 8 in order to obtain some available space.

Box C: Reporter Information

Line 8. Reporter's relationship to patient
Add a checkbox for "Parent."

Box E: Adverse Event Information

Box 2. How soon after vaccination did these event(s) start?
The question about the units of time from vaccination to onset of events is redundant since the form is asking for date of vaccination and date of onset of adverse events (the period of time between the two dates can be calculated). Suggest to add "Time of AE onset" similar to "Time of vaccination" in Box D.

Box 3. Date of onset
Suggest changing to "Date of AE onset."

Box 4. Did this event cause the patient to visit the doctor?
Suggest changing to "Did this event cause the patient to visit the doctor *or E. R.*?"

Box 7. Check below if the patient:

Died check box
Suggest changing "Date" to "Death Date."

Was hospitalized after vaccination
The form asks if the subject "Was hospitalized after vaccination." This question can be confusing. May we suggest asking that the line be changed to "Subject was hospitalized because of the adverse event" (not if hospitalization occurred after vaccination).
We also suggest adding: "Date discharged: _____/_____/_____" and/or
"Number of days hospitalized:_____."

Was already hospitalized and his/her stay was prolonged by_____ days
It may be difficult to specify the number of days that a hospitalization was prolonged. We suggest to only asking if the event prolonged the hospitalization.

Had life-threatening event AND Experienced permanent disability
To avoid confusion regarding a date of a life-threatening event listed below:
"List event" to be changed to "List event:_____* " and
"List disability" to be changed to "List disability:_____*." (Add underscores to create a more definitive writing space.

Suggest adding text "*Continue on a separate page if necessary" at the bottom of the box containing Death, Life-threatening event, etc. (Box 7)

Box F: Patient's Prior Health History

Box 1, 2, 3 and instructions for box 4, we suggest changing "recipient" to "patient" or "vaccinee." To avoid any confusion, we suggest all references to the vaccinee in question be made to the "patient" or other designations of the vaccinee. This will make Box F consistent with Box A, "Patient Information," at the top of the form that alludes to the patient.

Box 3. List any medications the .....
Suggest changing to "List any non-vaccine medications the....."

Instructions Line for Box 4
Change Instructions Line for Box 4 from: "List any other vaccines administered to the recipient within 4 weeks of the date given in Box D above:" to "List any other vaccines administered to the patient within 4 weeks before or after the date given in Box D above."

Box G: For Secondary Reporters' Use Only

Box 2. Tracking Number"
Suggest changing to "2. Tracking Number (Mfr file number)."

Box 4. Type of secondary report
It has been promulgated that follow-up numbers for individual reports could be printed in this box rather than as part of the "Tracking Number". If so, then may we suggest that "Follow-up No.____" similar to the appearance of follow-up numbers on a MedWatch form be added. An underscore following No. indicates where follow-up numbers should be mapped to by computer systems.

It appears that the designation CDC/FDA has been omitted from the Form VAERS-2. This was the only designation on the form that identified it as a CDC document as well as a FDA document. As such, the personal information on the form fell under the protection of pubic health patient privacy laws. It is suggested that this designation be returned to distinguish the duality of the form's purpose. In lower left hand corner of the entitled Form VAERS-1, suggest placing the "CDC/FDA" designation or "CDC/FDA VAERS-2 Form."

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on the proposed "Vaccine Adverse Event Reporting System; Revised Form VAERS-2" and thank you for your consideration.

Sincerely,

Maurice W. Harmon, Ph.D, RAC

for Ricky D. Smith
Acting Site Head,
Regulatory Affairs
and Authorized Official

RDS/MWH/kh

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

P.O. Box 1100, Rockville, MD 20849-1100
24-Hour Toll Free Information Line **800-822-7967**
This VAERS Form can be faxed toll-free to **877-721-0366**
Web site: http://www.vaers.org **e-mail:** info@vaers.org

For VAERS Use ONLY

Box A: Patient Information

1. Patient's Last Name, First Name, M.I.
2. Parent/Guardian Name *(if patient is under 18 years)*
3. Patient's Telephone Number
4. Patient's Occupation *(if patient is age 18 or over)*
5. Patient's Current Address
6. City | State | Zip
7. **Date of Birth** ____/____/____
8. **Age at vaccination**
9. Weight at birth *(if under age 5)* lbs., oz.
10. Sex ☐ M ☐ F
11. Race/Ethnicity *(check all that apply)*
☐ White ☐ American Indian, Eskimo, or Aleut
☐ Black ☐ Asian or Pacific Islander
☐ Hispanic (may be of any race) ☐ Other

Box B: Vaccine Provider Information

1. County where vaccine was administered:
2. Responsible Physician's Name:
3. Responsible Physician'sTelephone Number:
4. Responsible Physician's Facility Name:
5. Responsible Physician's Facility Street Address:
6. City | State | Zip
7. Vaccine was administered at:
☐ Physician's Office ☐ Military Facility
☐ Public Health Facility ☐ Workplace
☐ Hospital/Med. Center ☐ School/Daycare
☐ Other ____
8. Vaccine was purchased by provider with:
☐ Private Funds ☐ Other (please describe):
☐ Public Funds
☐ Military Funds

Box C: Reporter Information

1. Reporter is the person listed:
☐ In Box A ☐ In Box B ☐ Below
2. Reporter's Name
3. Reporter's Telephone Number:
4. Reporter's Facility/Organization Name
5. Reporter's Street Address
6. City | State | Zip
7. Date form completed: ____/____/____
8. Reporter's relationship to patient
☐ Family member ☐ Military Corpsman
☐ Nurse ☐ Pharmacist
☐ Physicians' Assistant
☐ Other Reporter (please describe below):

Box D: Vaccination Information

Provide information for all vaccines given on this date:	Vaccine Name	Manufacturer	Lot Number	Vaccination: Route	Vaccination: Site	Dose # in Series
Date of vaccination ____/____/____	a.					
	b.					
Time of vaccination ____ ☐ AM	c.					
	d.					
____ ☐ PM	e.					

Box E: Adverse Event Information

Describe the signs and symptoms that occurred after this vaccination and treatment, if any.
(Attach additional sheets if necessary)

DRAFT *NOT TO BE USED FOR REPORTING!*

Check below if the patient:
☐ Died
Date: ____/____/____
☐ Had life-threatening event
List event:
☐ Was hospitalized after vaccination
Date admitted: ____/____/____
☐ Was already hospitalized and his/her stay was prolonged by ____ days
☐ Experienced permanent disability
List disability:
☐ Required medical intervention to prevent any of the above outcomes.
☐ Experienced none of the above

How soon after vaccination did these event(s) start? *(check units)*
____ ☐ Hours ☐ Weeks ☐ Days ☐ Months

Did this event cause the patient to visit the doctor?
☐ No ☐ Yes If Yes, date of visit: ____/____/____

6. Has the patient recovered to his/her original state of health?
☐ Yes ☐ Not Yet ☐ No ☐ Unknown

Date of onset: ____/____/____

5. List results of relevant diagnostic procedures or lab testing:

Box F: Patient's Prior Health History

1. List recipient's pre-existing physician-diagnosed illnesses, allergies, and/or medical conditions.
2. List any acute illnesses the recipient was experiencing at the time of the vaccination(s) given in Box D.
3. List any medications the recipient was receiving at the time of the vaccination(s) given in Box D.

List any other vaccines administered to the recipient within 4 weeks of the date given in Box D above:

	4. Date vaccine given	5. Vaccine Name	6. Manufacturer	7. Lot Number	Vaccination: 8. Route	Vaccination: 9. Site	10. Dose # in Series
a.							
b.							

Box G: For Secondary Reporters' Use Only

1. Secondary reporter type
☐ Vaccine Manufacturer FDA Lic. # ____
☐ State Immunization Coord. State ____
☐ Immunization Registry Name: ____
2. Tracking Number
3. Date received
4. Type of secondary report
☐ Initial ☐ Follow-up ☐ Mfrs. 15-day
5. Does this report qualify as OMIC?
☐ Yes ☐ No

Form VAERS-2 (revised Jul 2001)

Healthcare providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the *Reportable Events Table* following immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of the immunization grant awards.

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